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EXAMINER	
ARNOLD, ERNST V	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,599	MEYER, DOMINIK	
	Examiner	Art Unit	
	Ernst V. Arnold	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37 and 39-42* is/are pending in the application.

4a) Of the above claim(s) *23-25 and 27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22,26,28-37 and 39-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/22/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Examiner acknowledges Applicant's election of Group II claims 1-37 and 39-42 as amended without traverse in the response filed on 5/4/07. Applicant was required to elect a fully disclosed composition and elected levobupivacaine as the neurotoxic substance and glycerin as the biocompatible solvent. Upon further consideration, the Examiner is expanding the search to include other amide local anesthetics.

Claims 1-37 and 39-42 are pending. Claims 38 and 43 have been cancelled. Claims 23-25 and 27 are withdrawn from consideration as being drawn to non-elected subject matter.

Comment: In claim 36, line 2, please correct "Adrenalin" to --- adrenaline ---.

Specification

Please insert at the top of page 1: ---This application is a 371 of PCT/CH02/00400 filed on 07/19/2002. ---

Information Disclosure Statement

The listing of references in the Search Report is not considered to be an information disclosure statement (IDS) complying with 37 CFR 1.98. 37 CFR 1.98(a)(2) requires a legible copy of: (1) **each foreign patent**; (2) **each publication or that portion which caused it to be listed**; (3) for each cited pending U.S. application, the application specification including claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion, unless the cited pending U.S. application is stored in the Image File

Wrapper (IFW) system; and (4) all other information, or that portion which caused it to be listed. In addition, each IDS must include a list of all patents, publications, applications, or other information submitted for consideration by the Office (see 37 CFR 1.98(a)(1) and (b)), and MPEP § 609.04(a), subsection I. states, "the list ... must be submitted on a separate paper." Therefore, the references cited in the Search Report have not been considered. Applicant is advised that the date of submission of any item of information or any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the IDS, including all "statement" requirements of 37 CFR 1.97(e). See MPEP § 609.05(a).

DE 19545180A has been considered only to the extent of the English language summary provided in the international search report.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-37 and 39-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 40 recite “neurotoxic substance”. It is unclear to the Examiner what is contemplated by Applicant to be a “neurotoxic substance”. The specification at page 3, lines 1-4, only provides a ‘generic’ description of what might be a neurotoxic substance. “Neurotoxic” merely describes the function of the substance rather than what it is. The chemical structure of this ‘substance’ is

unknown leaving it unclear as what it might be. Therefore, it is unclear to the Examiner exactly what constitutes a neurotoxic substance and consequently the claims are indefinite.

Claims 20-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 20 recites: "another substituted tetracaine". It is unclear to the Examiner which other substituted tetracaine is contemplated by Applicant. Claims 21 and 22 are indefinite because they are dependent on an indefinite base claim. The claims will be examined as they read on tetracaine or N-butyl tetracaine.

Claims 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 28 recites "derivatives inclusive of analogues". It is unclear to the Examiner the scope of "derivatives inclusive of analogues". The Examiner suggests removing the phrase. The claims will be examined as they read upon a phenol.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-22, 14, 26 and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Milligan et al. (Anaesthesia 1988, 43, 563-564) in view of Bawa et al. (US 6,261,547) and Goldenheim et al. (US 6,248,345) and Arias-Alvarez (US 4,657,764).

Applicant claims a method of treating joint pain comprising providing a neurotoxic substance dissolved in a biocompatible solvent and injecting the neurotoxic substance into a joint space such that neurolysis entails and wherein the local anesthetic is used jointly with a pH lowering additive.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Milligan et al. teach intra-articular bupivacaine for pain relief after arthroscopic surgery of the knee joint (title). Milligan et al. teach administering, by injection, sterile 20 mL solutions of 0.25% and 0.5% bupivacaine, which the Examiner interprets to mean that the "neurotoxic substance" was dissolved in a biocompatible solvent for injection (page 563, right column, middle paragraph). Since Applicant claims bupivacaine then it must be predominantly toxic to nociceptive nerve fibers but not systemically toxic and

less neurotoxic to motor and propioceptive nerve fibers than to sensitive nerve fibers. It is the Examiner's position that "intra-articular" encompasses the intra-capsular region or into the joint synovial pouch.

Bawa et al. teach the equivalence of bupivacaine and levobupivacaine in anesthetic compositions (claims 6 and 7).

Goldenheim et al. teach prolonged anesthesia in joints and body spaces and methods of treating localized pain comprising administering into an intra-articular joint a formulation comprising a local anesthetic such as bupivacaine, ropivacaine, dibucaine, etidocaine, tetracaine, lidocaine, xylocaine, procaine, chloroprocaine, prilocaine, mepivacaine and mixtures thereof thus establishing equivalency among these anesthetics (Claims 1-36). Goldenheim et al. teach adding a second active agent such as an enzyme, an anti-infective agent, an antibody, a diagnostic aid, a radio-opaque dye, a magnetic resonance imaging dye, a radiolabeled agent and mixtures thereof (Claims 15, 16, 18, and 22 for example).

Arias-Alvarez teaches the use of sodium bisulfite to treat symptoms of arthritis and arthritic conditions in humans (Abstract). Aqueous solutions of from about 1 to 15% by weight sodium bisulfite are prepared for oral consumption (column 3, lines 33-35).

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

1. While Applicant claims injecting the agent comprising a neurotoxic substance (local anesthetic) for treating post-operative joint pain at a concentration entailing neurolysis, Milligan et al. do not expressly teach a method of injecting the agent comprising a neurotoxic substance (local anesthetic) for treating joint pain at a concentration entailing neurolysis. However, instant claim 1 does not provide a concentration of the neurotoxic substance that would entail neurolysis and so it is the Examiner position that any concentration would do so. With respect to claims 4 and 11-19, 21 and 22 in which a concentration of the neurotoxic substance is recited, Milligan et al., suggests using higher concentrations of the anesthetic.

2. While Applicant claims using the local anesthetic jointly with a pH lowering additive ($NAHSO_3$), Milligan et al. do not expressly teach a method of wherein the local anesthetic is used jointly with a pH lowering additive that is a bisulfite (NaHSO3) in a concentration of at least 1% by weight. This deficiency is cured by the reference of Arias-Alvarez which teaches bisulfite for the treatment of the symptoms of arthritis (pain).

3. While Applicant claims a method wherein the local anesthetic is lidocaine, prilocaine, mepivacaine, levobupivacaine, ropivacaine, etidocaine, procaine, chloroprocaine, tetracaine or N-butyl tetracaine, Milligan et al. do not expressly teach a method wherein the local anesthetic is lidocaine, prilocaine, mepivacaine, levobupivacaine, ropivacaine, etidocaine, procaine, chloroprocaine, tetracaine or N-butyl tetracaine. This deficiency is cured by the teachings of Bawa et al. and

Goldenheim et al., which teach the equivalency of the local anesthetics to one of ordinary skill in the art.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to inject the agent for treating joint pain at a concentration entailing neurolysis, in the method of Milligan et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Milligan et al. teach that a concentration of 0.5% bupivacaine provided little analgesia and suggests the use of higher concentrations of bupivacaine (Page 564, discussion). It is then merely routine optimization for one of ordinary skill in the art to increase the dosage amount of the local anesthetic to provide adequate patient comfort and freedom from pain, which would entail neurolysis.

2. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to inject the agent (local anesthetic) for treating joint pain at a concentration entailing neurolysis wherein the local anesthetic is used jointly with a pH lowering additive that is a bisulfite ($NaHSO_3$) in a concentration of at least 1% by weight, as suggested by Arias-Alvarez, in the method of Milligan et al. and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because the art teaches the use of sodium bisulfite in the treatment of arthritis where the symptoms

include pain (Arias-Alvarez column 1, lines 42-56). Since the same compound in the same amount for the same purpose is taught in the art as instantly claimed then it would intrinsically lower the pH of the agent for treating joint pain to less than 3.5. The claim language of instant claim 5 recites "jointly" which does not preclude oral administration of the bisulfite.

3. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use the amide anesthetics, as taught by Bawa et al. and Goldenheim et al., in pure enantiomeric form in the method of Milligan et al. in the amount claimed and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Milligan et al. suggest using higher dosages of the anesthetic and the art teaches the equivalence of the amide anesthetics. Since the art teaches the equivalence of the amide anesthetics and it is merely judicious selection to pick the proper amide and routine optimization to arrive at the proper concentration especially when the art, Milligan et al., teaches higher dosages. Therefore, it is the Examiner's position that a concentration of local anesthetic > 4%; lidocaine > 6%; prilocaine > 3%; mepivacaine > 5%; bupivacaine > 1.5%; levobupivacaine > 5%; ropivacaine > 2%; etidocaine > 2%; procaine > 3%; chloroprocaine > 3%; tetracaine or N-butyl tetracine > 4% or 8% are all reasonably within routine optimization of the method of Milligan et al. by one of ordinary skill in the art. It is common sense that one of ordinary skill in the art would want the highest purity pharmaceutical agents in the preparation and that would encompass the enantiomeric forms as well.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claim Rejections - 35 USC § 103

Claims 1-8, 10, 11, 13, 26, 28, 35 and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Macek et al. (US 3,368,937).

Applicant claims a method of treating joint pain comprising providing a neurotoxic substance dissolved in a biocompatible solvent and injecting the neurotoxic substance into a joint space such that neurolysis entails and wherein the local anesthetic is used jointly with a pH lowering additive.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Macek et al. teach an injectable steroid anesthetic composition and teach administering a combined dosage of steroid and an aromatic amide (lidocaine and mepivacaine) (Column 1, lines 55-72). The route of administration can be intramuscular, intrasynovial, intra-ocular and soft tissue injection (column 1, lines 17-20). Macek et al. teach compositions comprising lidocaine, dissolved in water, dexamethasone, sodium bisulfite, phenol and water to create a water-soluble product (column 3, example 1, lines 22-40). Phenol is present as a bacteriological preservative (column 3, line 37 and claim 11, for example). The injectable solution consists essentially of a biocompatible solvent, water, about 5-20 parts by weight of lidocaine or mepivacaine and about 1-20 parts by weight of the steroid with water to 1 ml (Claims 1, 11 and 12). In the absence of evidence to the contray, the anesthetics used by Macek et al. are in their pure enantiomeric form. Since Applicant claims lidocaine then it must be predominantly toxic to nociceptive nerve fibers but not systemically toxic and less neurotoxic to motor and propioceptive nerve fibers than to sensitive nerve fibers.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. While Applicant claims a method of treating *post-operative joint pain* comprising providing a neurotoxic substance dissolved in a biocompatible solvent and injecting the neurotoxic substance into a joint space such that neurolysis entails, Macek

et al. do not expressly teach a method for treating *post-operative joint pain* comprising injecting an agent comprising a neurotoxic substance (local anesthetic) at a concentration entailing neurolysis. However, Macek teach such conditions as rheumatoid arthritis, bursitis and sprains *and the like* but does not specifically mention post-operative pain (column 1, lines 20-23).

2. While Applicant claims a method wherein the nociceptive nerve fibers are rendered pain-insensitive by the local anesthetic or the mixture of several local anesthetics for at least 14 days, Macek et al. do not expressly teach the duration of action of the injectable solution.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to treat post-operative pain with the composition and method of Macek et al. and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Macek et al. describe several types of painful joint trauma and suggests others ("and the like") such that one of ordinary skill in the art would immediately envision alleviation of joint pain associated with an operation.

2. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to treat post-operative pain with the composition and method of Macek et al. wherein the nociceptive nerve fibers are rendered pain-

insensitive by the local anesthetic or the mixture of several local anesthetics for at least 14 days and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Macek et al. teach using up to 20 parts by weight of the anesthetic (claim 1) which encompasses that which is instantly claimed and would therefore have the same duration of action.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claim Rejections - 35 USC § 103

Claims 1, 2, 5, 28-37 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Macek et al. (US 3,368,937) in view of Goldenheim et al. (US

6,248,345) and with respect to claims 34 and 37 Davis et al. (US 3,917,830) and with respect to claim 39 Herschler (US 4,296,104) and with respect to claims 28-30 Oakes et al. (US 5,061,485) and with respect to claims 31 and 32 Meuller (5,002,761) and with respect to claim 36 Chasin et al. (US 5,942,241) and with respect to claim 33 Klaveness (US 5,242,683).

Applicant claims a method of treating joint pain comprising providing a neurotoxic substance dissolved in a biocompatible solvent and injecting the neurotoxic substance into a joint space such that neurolysis entails and wherein the local anesthetic is used jointly with a pH lowering additive and in addition to the local anesthetic: 1) cresol; 2) a chloro cresol; 3) eugenol; 4) thymol; 5) x-ray contrast reagent; 6) glycerin; 7) vasoconstrictor; and 8) DMSO, are added.

Determination of the scope and content of the prior art

(MPEP 2141.01)

The references of Macek et al. and Goldenheim et al. are discussed in detail above and those discussions are hereby incorporated by reference.

Oakes et al. teach the equivalence of phenol, cresol , m-, o-, p-chlorocresol etc... as germicidal agents (column 5, lines 60-68 and claim 29 for example).

Herschler teaches DMSO as a known penetration enhancer for pharmaceutical agents such as analgesics, steroids and anti-inflammatory agents (column 4, lines 41-47).

Davis et al. teach an injectable steroidal anesthetic wherein the injection medium comprises propylene glycol, glycerol or glycerol formal of greater than 50% of the total injection (claims 1-4).

Mueller et al. teach the equivalence of thymol and eugenol as preservatives (column 4, lines 11-16 and claim 18).

Chasin et al. teach formulations and methods for providing prolonged local anesthesia comprising vasoconstricting agents such as epinephrine (which is synonymous with adrenaline), norepinephrine and phenylphrine and local anesthetics such as bupivacaine (Abstract, column 9, lines 60-65; claims 1-8, 11, 12 and 23-33, for example).

Klaveness teaches contrast media comprising a paramagnetic agent and an iodinated agent for X-ray and MRI (Title; abstract). Barium and iodine are taught as contrast agents (column 1, lines 15-18). The paragmagnetic metal can be gadolinium (Claims 1 and 9).

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

1. While Applicant claims a method of treating post-operative joint pain comprising providing a neurotoxic substance dissolved in a biocompatible solvent and injecting the neurotoxic substance into a joint space such that neurolysis entails and wherein the local anesthetic is used jointly with a pH lowering additive and in addition to the local anesthetic: 1) cresol; 2) a chloro cresol; 3) eugenol; 4) thymol; 5) x-ray

contrast reagent; 6) glycerin; 7) vasoconstrictor; and 8) DMSO, are added, Macek et al. do not expressly teach the addition of these components in a method of treating post-operative joint pain but as explained above, Macek et al. suggest treating pain in joints which would include post-operative joint pain.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add 1) cresol; 2) a chloro cresol; 3) eugenol; 4) thymol; 5) x-ray contrast reagent; 6) glycerin; 7) vasoconstrictor; and 8) DMSO, as suggested by Oakes, Herschler, Davis, Mueller, Chasin and Klaveness, to the method of Macek et al. and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because: 1 and 2) Macek et al. teach phenol as a preseservative which renders other phenols, such as those taught by Oakes et al. obvious to one of ordinary skill in the art; 3 and 4) eugenol and thymol are also taught as preservatives by Meuller et al. and are phenols and would be obvious to one of ordinary skill in the art; 5) Goldenheim teaches the addition of diagnostic agents to intra-articular joint a formulations comprising a local anesthetic but does not specifically name them and Klaveness cures that deficiency by teaching the types of X-ray contrast reagents known to one of ordinary skill in the art; 6) Davis teaches glycerol as a medium for injection of these solutions which is known to one of ordinary skill in the art; 7) Chasin teach that addition of vasoconstrictive agents

might greatly prolong local anesthetic activity (column 9, lines 4-25); and 8) Herschler teaches DMSO as a known penetration enhancer. It is the Examiner's position that with the exception of the vasoconstrictor the other additional components are readily known to one of ordinary skill in the art. The motivation to add the vasoconstrictor comes from the teaching that it can provide prolonged anesthetic activity.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).s

1. Claims 1, 2 and 40-42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 50 and 51 of copending Application No. 11/722,779. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed subject matter is embraced by or embraces the subject matter of the co-pending application. Instant claim 1 is drawn to a method of treating joint pain comprising providing a neurotoxic substance dissolved in a biocompatible solvent and injecting the neurotoxic substance into a joint space such that neurolysis entails. Copending claim 50 is drawn to a method of treatment of pain with resiniferatoxin dissolved in a solvent compatible with the body in a volume of 0.1 to 150 mL and injected into the intracapsular region such that neurolysis occurs. Instant claim 42 recites a period of 14 days and copending claim 51 recites at least 14 days. One of ordinary skill in the art would have recognized the obvious overlap in subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

2. Claims 1, 2 and 40-42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 39-42 of copending Application No. 11/722,857. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed subject matter is embraced by or embraces the subject matter of the co-pending application. Instant claim 1 is drawn to a method of treating joint pain comprising providing a neurotoxic substance dissolved in a biocompatible solvent and injecting the neurotoxic substance into a joint space such that neurolysis entails. Copending claims 39, 40, 41 and 42 recite a method for the treatment of articular pain wherein an agent is injected into the intracapsular region of a joint affected by pain; wherein the agent is dissolved in a solvent compatible with the body and 0.1 to 150 ml of the solution is injected into intracapsular region; nociceptive fibers are made insensitive to pain for at least 14 days; and neurolysis occurs. One of ordinary skill in the art would have recognized the obvious overlap in subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Claims 1, 2 and 40-42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 94-96 of copending Application No. 11/722,484. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed subject

matter is embraced by or embraces the subject matter of the co-pending application. Instant claim 1 is drawn to a method of treating joint pain comprising providing a neurotoxic substance dissolved in a biocompatible solvent and injecting the neurotoxic substance into a joint space such that neurolysis entails. Copending claims 94-96 recite a method for the treatment of joint pain wherein an agent is injected into the intracapsular region or into the joint capsule of a joint affected by pain; wherein the agent is dissolved in a solvent compatible with the body and 0.1 to 150 ml of the solution is injected into intracapsular region or into the joint capsule of a joint affected by pain; nociceptive fibers are made insensitive to pain for at least 14 days; and neurolysis occurs. One of ordinary skill in the art would have recognized the obvious overlap in subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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